

**REMARKS**

Claims 1-51 and 76-144 are pending herein. By the Office Action, claims 4, 13-14, 26-49, 54-110 and 122-144 are withdrawn from consideration; the specification is objected to; claims 1-3 and 15-16 are rejected under 35 U.S.C. §102; and claims 1-12, 15-25, 50-51 and 111-121 are rejected under 35 U.S.C. §103. By this Amendment, the specification is amended.

I. **Formal Matters**

An Information Disclosure Statement with Forms PTO-1449 was filed on January 31, 2000. Although the first Office Action enclosed copies of the Forms PTO-1449, the Form 2 of 4 was not initialed by the Examiner to acknowledge the fact that the Examiner has considered the cited information. This deficiency has repeatedly been pointed out in Applicant's previous responses, but has not been addressed by the Patent Office. The Examiner is again requested to initial and return to the undersigned a copy of the subject Form PTO-1449. For the convenience of the Examiner, a copy of that form is attached.

II. **Restriction/Election Requirement**

Claims 4, 13-14, 26-49, 54-110 and 122-144 are withdrawn from consideration as subject to Restriction and Election Requirements.

A. **The Requirements are Clearly Improper and Must be Withdrawn**

Applicants again assert that both the Restriction Requirement and the Election of Species Requirement are clearly improper, and should be withdrawn. The Requirements are improper at least because there would be no burden on the Examiner to search and examine the full scope of the pending claims.

Applicants respectfully assert that search and examination of the entire application could be conducted without undue burden on the Examiner, thus avoiding delay and expense to Applicants. This is evidenced by the fact that the Patent Office has already searched and

examined the full scope of all of the original claims. The application was already subjected to a first Restriction Requirement, mailed January 3, 2001, to which Applicants filed a response on January 24, 2001. Based on Applicants' response, the Examiner previously indicated that the original Restriction Requirement was withdrawn, and all of the pending claims were examined on the merits. See April 6, 2001, Office Action at page 2.

Since that first Restriction Requirement, the Patent Office has issued three Office Actions, all of which addressed all of the pending claims on the merits. See Office Actions dated April 6, 2001, October 9, 2001, and March 13, 2002. Applicants timely responded to each of the Office Actions and, in response to an Advisory Action, filed a Request for Continued Examination on November 13, 2002.

As evidenced by the already lengthy prosecution history, the Patent Office has already searched and examined all of the pending claims, on at least three separate occasions. Because all of the claims have been searched and examined, there should be no further substantial burden on the Examiner to continue to search and examine the entire claimed invention. Maintaining the Restriction and Election of Species Requirements would thus only work a manifest injustice upon Applicants. The Requirements should thus be withdrawn.

B. The Requirements are Traversed

With respect to the Restriction Requirement, Applicants continue to assert that the basis for the Restriction Requirement is improper, at least based on the inter-relation between the identified inventions, and the prior search and examination of this application. Applicants request reconsideration and withdrawal of the Restriction Requirement, and reserve the right to Petition the propriety of the Restriction Requirement.

With respect to the Election of Species Requirement, Applicants understand that upon search, examination and allowance of the elected species, search and examination will continue as to the non-elected species within the scope of the generic claims.

### III. Rejections Under 35 U.S.C. §102

#### A. Casey

Claims 1-3 and 15 are rejected under 35 U.S.C. §102(b) over Casey. The Office Action asserts that Casey discloses the claimed invention, for example at the Abstract, col. 3, lines 55-64, and Examples 1 and 26. Applicants respectfully traverse this rejection.

Independent claim 1 is directed to a method of applying at least one agent selected from the group consisting of bioactive materials, flavorants, polymerization initiators, and polymerization rate modifiers to an applicator tip for an adhesive applicator, comprising: dissolving or dispersing said agent in a low boiling point solvent to form a solution; applying said solution to said applicator tip; and drying said applicator tip; wherein the low boiling point solvent comprises methanol. Such a method is nowhere disclosed in Casey.

In contrast to the claimed invention, Casey is directed to the production of specific diblock and triblock copolymers. Production of the copolymers, including by use of an initiator, is disclosed in Casey in the Abstract and col. 3, lines 55-64, as cited in the Office Action. Casey then separately discloses that the formed polymer can be subsequently dissolved in a solvent such as methanol, and applied to a suture thread by dipping the suture thread into the solvent mixture. See Examples 1 and 26. Once the thread is dried, the result is a polymer-coated thread.

However, Casey does not disclose at least the instant claim limitation of applying the at least one agent to an applicator tip for an adhesive applicator. This limitation is stated in the preamble of claim 1, but is drawn into the body of the claim by the subsequent references to the applicator tip. At most, Casey teaches applying the polymer to a suture thread. The suture thread is not an applicator tip, and is not an applicator tip for an adhesive applicator. These limitations are expressly stated in claim 1, and cannot be ignored by the Office Action.

Because Casey does not disclose this limitation of the claimed invention, Casey cannot anticipate the claimed invention.

Further, Casey does not disclose at least the instant claim limitations of dissolving or dispersing said agent in a low boiling point solvent to form a solution and applying said solution to said applicator tip. At most, Casey discloses forming a polymer by using an initiator, and then separately dissolving that polymer in a solvent. However, Casey does not disclose that any initiator is retained as a separate component in the resultant polymer, such that it becomes dissolved in the solvent. Nor does Casey disclose separately dissolving additional initiator in the solvent along with the polymer. Accordingly, Casey dissolves only polymer, but not initiator, in the solvent for subsequent application to the suture thread. Because Casey does not disclose this limitation of the claimed invention, Casey cannot anticipate the claimed invention.

Even where Casey discloses the use of methanol, which is required in the instant claims, Casey does so in an entirely different context from the claimed invention. For example, in Example 1 Casey discloses the use of methanol, but only as a means to purify the formed polymer materials. Casey nowhere describes that the solution of methanol and one of bioactive materials, flavorants, polymerization initiators, and polymerization rate modifiers is maintained, and applied to an applicator tip as claimed.

Accordingly, Casey fails to disclose all of the limitations of the claimed invention, and thus fails to anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

B. Engelson

Claims 1-2 and 15-16 are rejected under 35 U.S.C. §102(b) over Engelson. The Office Action asserts that Engelson discloses the claimed invention, for example at the Abstract and col. 4, lines 31-67. Applicants respectfully traverse this rejection.

Independent claim 1 is discussed above. The claimed method is nowhere disclosed in Engelson.

In contrast to the claimed invention, Engelson is directed to the application of a thin, very slippery polymer coating to the outer surface of a catheter to assist in use of the catheter. The coating is formed by applying to the catheter a solution of polymer or oligomer in solvent, optionally with an initiator applied at the same or a later time. See Engelson at Abstract and col. 4, lines 31-67.

However, Engelson, like Casey discussed above, does not disclose at least the instant claim limitation of applying the at least one agent to an applicator tip for an adhesive applicator. This limitation is stated in the preamble of claim 1, but is drawn into the body of the claim by the subsequent references to the applicator tip. At most, Engelson teaches applying a solution of solvent, polymer or oligomer, and optional initiator to the outer surface of a catheter. The catheter is not an applicator tip, and is not an applicator tip for an adhesive applicator. These limitations are expressly stated in claim 1, and cannot be ignored by the Office Action. Because Engelson does not disclose this limitation of the claimed invention, Engelson cannot anticipate the claimed invention.

Accordingly, Engelson fails to disclose all of the limitations of the claimed invention, and thus fails to anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

#### IV. Rejections Under 35 U.S.C. §103

##### A. Claims 1-12, 15-25, 50-51 and 111-121

Claims 1-12, 15-25, 50-51 and 111-121 are rejected under 35 U.S.C. §103(a) over Engelson in view of WO '598 or Engelson in view of WO '797. Because the disclosures of WO '598 and WO '797 are similar, at least with respect to their applicability to the present

claims, the references will be addressed together. Applicants respectfully traverse these rejections.

Independent claim 1 is directed to a method of applying at least one agent selected from the group consisting of bioactive materials, flavorants, polymerization initiators, and polymerization rate modifiers to an applicator tip for an adhesive applicator, comprising: dissolving or dispersing said agent in a low boiling point solvent to form a solution; applying said solution to said applicator tip; and drying said applicator tip; wherein the low boiling point solvent comprises methanol. Independent claim 50 is directed to a method of applying at least one agent selected from the group consisting of bioactive materials, flavorants, polymerization initiators, and polymerization rate modifiers to an applicator tip for an adhesive applicator, comprising: dissolving, dispersing or suspending said agent in a liquid medium to form a suspension or solution; combining said suspension or solution and said applicator tip in a vessel; sealing said vessel; applying one of a vacuum or pressure to said vessel to degas air trapped in said applicator tip; releasing said vacuum or pressure; and optionally drying said applicator tip. Such methods are nowhere taught or suggested by the cited references.

1. Engelson Does Not Teach or Suggest the Claimed Invention

Engelson is discussed in detail above. Engelson discloses the application of a thin, very slippery polymer coating to the outer surface of a catheter to assist in use of the catheter. The coating is formed by applying to the catheter a solution of polymer or oligomer in solvent, optionally with an initiator applied at the same or a later time. See Engelson at Abstract and col. 4, lines 31-67.

As discussed above, Engelson does not disclose at least the instant claim limitation of applying the at least one agent to an applicator tip for an adhesive applicator. At most, Engelson teaches applying a solution of solvent, polymer or oligomer, and optional initiator

to the outer surface of a catheter. The catheter is not an applicator tip, and is not an applicator tip for an adhesive applicator.

In fact, Engelson nowhere discloses, or even suggests, that the catheter could or should be used for applying an adhesive composition. Engelson nowhere mentions adhesives in any context, much less as a material to be applied using the catheter.

Still further, Engelson expressly discloses that the polymer film applied to the catheter, should be applied only to the outer surface of the catheter for the purpose of making the catheter very slippery. At col. 4, lines 31-36, Engelson discloses various methods for applying the polymer film to the catheter. In the embodiment where the catheter is dipped into the solution, Engelson expressly discloses that the open ends of the catheter can be sealed, if desired. The purpose of applying the polymer film to make the catheter very slippery is disclosed at, for example, the Abstract.

Accordingly, Engelson as a whole teaches applying a polymer film to an outer surface of a catheter. The catheter is not an applicator for an adhesive material, and the polymer film is not even applied to an applicator tip of such an adhesive applicator. Nowhere does Engelson teach or suggest modifying its disclosure to practice the claimed invention.

## 2. WO '598 and WO '797 Do Not Overcome the Deficiencies of Engelson

The Office Action states that Engelson does not disclose some of the specific polymerization initiators of the dependent claims, but cites WO '598 and WO '797 as disclosing those initiators. The Office Action also states that WO '598 and WO '797 are directed to catheters, applicators, and applicator tips, and are thus combinable with Engelson. Applicants disagree.

### a. There is no Motivation to Combine the References

It is axiomatic in patent law that two references can not be combined to render obvious the claimed invention where there is no motivation in the references or elsewhere to make the

asserted combination. For example, the Federal Circuit held in In re Oetiker that "[t]here must be some reason, suggestion or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). See also In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.").

That is, it is not enough that a reference may be capable of being modified so as to arrive at a claimed invention. To the contrary, the prior art must have suggested the desirability of such modification to one of ordinary skill in the art at the time the invention was made. As stated in Interconnect Planning Corp. v. Feil:

When prior art references require selective combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the patent itself. There must be 'something in the prior art as a whole to suggest the desirability, and thus the obviousness of making the combination.' Critical to the analysis is an understanding of the particular results achieved by the new combination.

774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) (citations omitted).

In the present case, Engelson and WO '598 and WO '797 are improperly combined, because there is no motivation to combine the references. As described above, Engelson is directed to methods for applying a thin polymer film to the outer surface of a catheter to make the catheter very slippery. In contrast, WO '598 and WO '797 are directed to applicators for applying a polymerizable adhesive material, where the applicators include an applicator tip that includes a polymerization initiator for the polymerizable adhesive material. Nowhere does either reference teach or suggest that the polymerization initiators of WO '598 and WO '797 could or should be used as the polymerization initiators required in Engelson to form the polymer film, or vice versa.

In the absence of any motivation to combine the cited references, one of ordinary skill in the art would not have looked to the divergent teachings of WO '598 and WO '797 as a means to improve upon the polymer film coating process of Engelson. Because the references are improperly combined, the rejection must be withdrawn.

b. Even if Combined, the References Would Not Provide the Claimed Invention

Even if improperly combined in the manner asserted in the Office Action, the result still would not have been the claimed invention. The Office Action states that the motivation and reason for combining the references, is because WO '598 and WO '797 disclose additional initiators within the scope of the instant dependent claims. However, even if combined in the manner asserted in the Office Action, the result would not be the claimed invention.

If Engelson and WO '598 and WO '797 were combined in the manner of the Office Action, the result would be to use the polymerization initiators of WO '598 and WO '797 in the processes of Engelson. That is, the combination would be to use the initiators of WO '598 and WO '797 to polymerize the polymer film that Engelson applies to the outer surface of the catheter. However, for all of the reasons described above, that combination would not be applying the initiator to an applicator tip for an adhesive applicator, as claimed.

Accordingly, even if improperly combined, the resultant combination would not have rendered obvious the claimed invention.

3. Conclusion

Accordingly, for at least these reasons, the references cannot have rendered obvious to one of ordinary skill in the art the invention of independent claims 1 and 50, and the claims dependent therefrom. Reconsideration and withdrawal of the rejections with respect to these claims are respectfully requested.

B. Claims 7-9

Claims 7-9 are rejected under 35 U.S.C. §103(a) over Engelson in view of WO '598 and further in view of Ren, or over Engelson in view of WO '797 and further in view of Ren. Because the disclosures of WO '598 and WO '797 are similar, at least with respect to their applicability to the present claims, the references will be addressed together. Applicants respectfully traverse these rejections.

Independent claim 1 is discussed in detail above. Likewise, the application of Engelson and WO '598 and WO '797 to the claimed invention is discussed in detail above.

The Office Action argues that Engelson, WO '598 and WO '797 teach or suggest all of the limitations of the claimed invention, except for the use of crystal violet. The Office Action then argues that Ren discloses the use of crystal violet as a polymerization initiator in a polymer composition. The Office Action argues that it would have been obvious to use the crystal violet initiator of Ren in the combination of Engelson, WO '598 and WO '797.

Applicants disagree.

For all of the reasons discussed above, Engelson, WO '598 and WO '797 are improperly combined, and in any event would not have rendered obvious the invention of independent claim 1. Ren's mere disclosure of crystal violet as a polymerization initiator fails to overcome the deficiencies of Engelson, WO '598 and WO '797, and would not have rendered obvious the claimed invention.

Like WO '598 and WO '797, above, Ren is also improperly combined with Engelson, because there is no motivation to combine the references. While Engelson is directed to methods for applying a thin polymer film to the outer surface of a catheter to make the catheter very slippery, Ren is directed to methods for forming highly colored polymer bodies. This is achieved in Ren by using a color precursor and an onium salt, such that the color precursor is converted to its colored form. Nowhere does either reference teach or suggest

that the highly colored polymer bodies of Ren, or components thereof, could or should be used as the polymerization initiators required in Engelson to form the polymer film, or vice versa. Neither reference teaches or suggests that the crystal violet initiator of Ren by itself could or should be used to polymerize the materials of Engelson, and neither reference teaches or suggests that the highly colored polymers of Ren would be suitable for the very thin and slippery film desired in Engelson.

In the absence of any motivation to combine the cited references, one of ordinary skill in the art would not have looked to the divergent teachings of WO '598, WO '797 and Ren as a means to improve upon the polymer film coating process of Engelson. Because the references are improperly combined, the rejection must be withdrawn.

Furthermore, even if improperly combined in the manner asserted in the Office Action, the result still would not have been the claimed invention. The Office Action states that the motivation and reason for combining the references, is because WO '598 and WO '797 disclose additional initiators within the scope of the instant dependent claims, and Ren discloses that crystal violet is a polymerization initiator. However, even if combined in the manner asserted in the Office Action, the result would not be the claimed invention.

If Engelson, WO '598, WO '797 and Ren were combined in the manner of the Office Action, the result would be to use the crystal violet polymerization initiator of Ren in the processes of Engelson. There would be no apparent use of the disclosures of WO '598 and WO '797, since those references likewise are only cited for various polymerization initiators. Thus, the combination would be to simply use the crystal violet initiator of Ren to polymerize the polymer film that Engelson applies to the outer surface of the catheter. However, for all of the reasons described above, that combination would not be applying the initiator to an applicator tip for an adhesive applicator, as claimed.

Accordingly, even if improperly combined, the resultant combination would not have rendered obvious the claimed invention.

Accordingly, for at least these reasons, the references cannot have rendered obvious to one of ordinary skill in the art the invention of independent claims 1, and claims 7-9 dependent therefrom. Reconsideration and withdrawal of the rejections with respect to these claims are respectfully requested.

V. Conclusion

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,



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WPB:JSA

Attachment:

Form PTO-1449

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